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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,811	01/03/2002	John Anthony Armour	16-007	2632

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,811

Applicant(s)

ARMOUR, JOHN ANTHONY

Examiner

Ethan C. Whisenant

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-28, 30-42, 44 and 47-52 is/are rejected.
- 7) ☒ Claim(s) 29, 43, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The applicant's Preliminary Amendment has been entered. The applicant's Preliminary Amendment was received on 30 AUG 01 and have been entered as paper no. 1 1/2 (Amdt. A). Following the entry of the Preliminary Amendments **Claim(s) 27-52** is/are pending.

SEQUENCE Rules

2. This application fails to comply with the sequence rules. See the attached notice to comply with the sequence rules.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections under 35 USC § 102

4. **Claim(s) 27-28, 30-33, 35-42, 44, 48-52** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al. [US 5,942,391 (1999)].

Claim 27 is drawn to a method of screening for copy number of target nucleic acid sequences in a sample of genetic material.

Zhang et al. teach a method of screening for copy number of target nucleic acid sequences in a sample of genetic material which comprises all of the limitations set forth in Claim(s) 27-28, 30-33, 35-38.

See, for example, at least the following figure(s)/passage(s) in Zhang et al.: Figure(s) 1 and 7; Column 3, beginning at about line 9 - Column 4, ending at about line 29; Column 6, lines 10-13 [numbers (3) and (4)]; Column 7, beginning at about line 29 and ending at about line 47; and finally note Column 18, beginning at about line 37 to the end of the column.

Claim 51 is drawn to a set of probes for use in performing the method according to Claim 27. **Claim 52** is drawn to a kit for performing the method according to Claim 27 wherein said kit comprises a probe set, amplification primers and means to enable amplification and analysis of amplification product(s). Zhang et al. teach a set of probes as well as a kit comprising all of the structural limitations recited in Claims 51-52, see especially Column 25, beginning at about line 9 and ending at about line 47.

35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

6. **Claim(s) 34** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. [US 5,942,391 (1999)] as applied above and further in view of Concannon [US 5,942,391 (1998)].

Claim 34 is drawn to an embodiment of the method of Claim 27 wherein the method is used to screen sequences of different exons in a eukaryotic gene.

Zhang et al. teach a method comprising all of the limitations recited in Claim 34 except these authors do not explicitly teach screen sequences of different exons in a eukaryotic gene. However, Concannon do teach screening sequences of different exons in a eukaryotic gene in order to identify mutations in the human ATM gene. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method described by Zhang et al. wherein the sequences of different exons in the human ATM gene are screened in order to identify mutations in the human ATM gene as suggested by Concannon.

- 7.** Claim(s) 47 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. [US 5,942,391 (1999)] as applied above and further in view of Yamane et al. [US 5,601,976 (1997)].

Claim 47 is drawn to an embodiment of the method of Claim 27 wherein the unbound probes and primers are washed away following hybridization and prior to analysis.

Zhang et al. teach a method comprising all of the limitations recited in Claim 27 except these authors do not explicitly teach washing away the unbound probes and primers following hybridization and prior to analysis. These authors do teach washing away unbound probes following hybridization and ligation and prior to analysis but not the primers following amplification. However, Yamane et al. teach a method wherein unbound primers are washed away following amplification and prior to analysis. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method described by Zhang et al. wherein both unbound probes and primers are washed away following hybridization and prior to analysis. One of ordinary skill in the art at the time of the invention would have been motivated to make this modification in view of the advantages of the method of Yamane et al. outlined in Column 1-2.

CLAIM OBJECTIONS

- 8.** Claim(s) 29, 43, 45-46 is /are objected to because it is dependent upon a rejected independent base claim.

CONCLUSION

- 9.** Claim(s) 27-52 is/are rejected and/or objected to for the reason(s) set forth above.

- 10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general

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nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



ETHAN C. WISENANT
PRIMARY EXAMINER

Application No.: 09/914,811

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- 7. Other: _____

Applicant Must Provide:

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- An initial or substitute paper copy of the "Sequence Listing", as well as, an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).